Appendix B

Summary of Human Clinical Trials of Foodborne Pathogens

Potential Surrogate Pathogens for *E. coli* O157:H7 (strain or serotype)	Number of Dose Groups	Total Number of Human Volunteers	Lowest Dose Tested and with Illness	Reference
1. *S. dysenteriae* (M131)[a]	4	30[b]	10, 10	Levine et al. 1973
2. *S. dysenteriae* (A-1)[c]	2	10	$2x10^2$, $2x10^2$	Levine et al. 1973
3. *S. flexneri* (2457T)[d]	5	43	10^4, 10^4	DuPont et al. 1969
4. *S. flexneri* (2457T)	4	197	10^5, 10^5	DuPont et al. 1972
5. *S. sonnei* (53G)[e]	1	20, 38	500, 500	DuPont et al. 1989
6. Enteropathogenic *E. coli* wild type (O111:NM, B1718)[f] + bicarbonate	3	13[g]	$5x10^8$, $5x10^8$	Bieber et al. 1998
7. Enteropathogenic *E. coli* (O142:H6)[h] + bicarbonate	3	15[i]	10^6, 10^6	Levine et al. 1978
8. Enteropathogenic *E. coli* (O128:H6)[j] + bicarbonate	3	15	Avirulent at 10^{6-10}	Levine et al. 1978
9. Enteropathogenic *E. coli* (O127:H6)[k] + bicarbonate	2	9	10^6, 10^{10}	Levine et al. 1978
10. Enterotoxigenic *E. coli* (O78:H11)[l] + bicarbonate	2	14[m]	10^6, 10^6	Evans et al. 1978
11. Enterotoxigenic *E. coli* (non-typable)[n]	3	14[o]	10^6, 10^8	Levine et al. 1977
12. Enterotoxigenic *E. coli* (O148:H28)[p]	2	17[q]	10^6, 10^6	Levine et al. 1979
13. Enterotoxigenic *E. coli* (O25:NM)[r]	1	6[o]	10^9, 10^9	Levine et al. 1979

Potential Surrogate Pathogens for *E. coli* O157:H7 (strain or serotype)	Number of Dose Groups	Total Number of Human Volunteers	Lowest Dose Tested and with Illness	Reference
14. Infant diarrheal *E. coli* (O111, B4, H)	4	46[s]	10^6, 10^6	June et al. 1953
15. Infant diarrheal *E. coli* (O111, B4, H)	4	46[s]	10^8, 10^8	June et al. 1953
16. Infant diarrheal *E. coli* (O111, B5)	1	1[t]	10^8, 10^8	Ferguson and June 1952, citing Neter 1950
17. Infant diarrheal *E. coli* (O111, B5)	1	6	10^9, 10^9	Ferguson and June 1952, citing Kirby 1950
18. Infant diarrheal *E. coli* (O111, B5)	1	3	Avirulent at 10^{10}	Ferguson and June 1952, citing Kirby 1950
19. Commensal *E. coli*	2	19	Avirulent at ~10^{10}	June et al. 1953
20. Commensal *E. coli*[u] + bicarbonate	1	4	Avirulent at 10^{10}	Levine et al. 1978

[a]Isolated from feces of patient in Guatemala with severe dysentery from 1970 pandemic and administered in milk.

[b]Fasting male prison volunteers.

[c]Isolated from feces of patient in Guatemala with mild dysentery and administered in milk.

[d]Isolated from feces of patient in Japan and administered in milk.

[e]Isolated from feces of 5-year-old patient in Japan and administered in milk.

[f]Isolated and administered in phosphate buffered saline with sodium bicarbonate.

[g]Fasting volunteers, 18 to 48 years of age.

[h]Isolate infant diarrheal strain from UK hospitals (Glasgow, E851/71) and administered with bicarbonate in saline; virulent at each of 3 doses administered.

[i]Healthy adult volunteers, mean age 24 years, 90-minute fast pre- and post-treatment.

[j]Isolate infant diarrheal strain from UK hospitals (Teesside, E74/68) and administered with bicarbonate in saline; avirulent in 15 healthy adults tested.

[k]Isolate infant diarrheal strain from UK residential nursery (Taunton, E2348/69) and administered with bicarbonate in saline; virulent at 1 of 2 doses administered.

[l]Isolated from severe non-Vibrio cholera case in Bangladesh.

[m]Male and female student volunteers, mean age 23.

[n]Isolated from physician traveling in Mexico with traveler's diarrhea and administered in milk with 2.5 hour fast intervals before and after treatment.

[o]Student volunteers, 18 to 29 years of age.

[p]Isolated from U.S. soldier in Vietnam with diarrhea and administered with bicarbonate in buffer.

[q]Healthy adult volunteers, mostly students, mean age 25, range 18 to 41 years of age.

[r]Isolated from physician traveling in Mexico with traveler's diarrhea and administered in milk with 2.5 hour fast intervals before and after treatment.

[s]Presumably fasting male prison volunteers, 16 to 48 years of age.

[t]Two-month old infant administered 10^8 organisms and developed diarrhea and weight loss within 24 hours.

[u]Nonpathogenic isolate from healthy laboratory scientist, administered in bicarbonate at 10^{10} in saline; avirulent in all four volunteers.

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